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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,379	11/19/2003	Bruce M. Frankel	7177USO1	6700
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PAUL D. YASGER ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008				
EXAMINER RAMANA, ANURADHA				
ART UNIT 3733		PAPER NUMBER		
NOTIFICATION DATE 07/22/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/717,379

Applicant(s)

FRANKEL ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 21-28 and 31-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 21-22 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-28 and 31-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorek (US 6,752,809).

Gorek discloses a method of introducing fluid into a bone including the steps of: advancing a threaded cannula or "bone tap" 100 having openings 110 communicating with a passage 104 utilizing an applicator or "driver" 118; introducing fluid or "bone cement" to the bone through the openings; and introducing a bone screw into an opening created by the cannula or bone tap (Figs. 1a-1c, col. 2, lines 53-67, col. 3, col. 4, 1-63, col. 5, lines 35-67 and cols. 6-8).

Claims 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. (US 6,610,079).

Li et al. disclose a method of introducing a fluid into bone including the steps of: advancing a rivet or "bone tap" 70 into bone, the rivet having screw threads and openings; introducing fluid or polymer or "bone cement" into the surrounding bone through openings in the bone tap; and introducing a fastener such as a suture through an opening formed by the bone tap (Figs. 1B, 4B, 5A and 6, col. 2, lines 58-61, col. 7, lines 58-67, col. 8, col. 9 and col. 10, lines 1-16).

Claims 33-34, 36-38, 40, 42, 44-47, 49 and 51-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniel et al. (US 6,622,731).

Daniel et al. disclose a method of introducing fluid into bone including the steps of: advancing an introducer or "bone tap" 292 into bone, the bone tap including a passage and one or more openings (312) communicating with the passage and threading (310) located near a distal end of the bone tap; introducing fluid or "cement" through the bone tap utilizing a fluid delivery system such as a syringe; and coupling a handpiece or "driver" to the bone tap to remove the bone tap from bone (Figs. 22-24C, col. 20, lines 25-59, col. 21, lines 59-67, cols. 22-23 and col. 24, lines 1-3).

The steps of: introducing fluid to a first location; moving the bone tap and introducing fluid to a second location are inherent in the disclosure of Daniel et al. since a patient could have multiple sites requiring treatment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorek (US 6,752,809) in view of Tague et al. (US 6,599,293).

Gorek discloses all elements of the claimed invention except for providing a medicament or drug in the bone cement.

It is well known to mix antibiotics or other desired drugs in bone cement so that when the bone cement is applied to a specific surgical site, the drugs leach out and are delivered directly to the surgical site as demonstrated by Tague et al. (col. 1, lines 32-37).

Accordingly it would have been obvious to have mixed a desired drug into the bone cement prior to delivery of the bone cement utilizing the method of Gorek since it

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was well known in the art to mix a specific drug in bone cement prior to delivery of the bone cement to a specific surgical site so that the drug is delivered directly to the surgical site.

The method steps of claim 25 are rendered obvious by the above discussion.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US 6,610,079) in view of Tague et al. (US 6,599,293).

Li et al. disclose all elements of the claimed invention except for providing a medicament or drug in the bone cement.

It is well known to mix antibiotics or other desired drugs in bone cement so that when the bone cement is applied to a specific surgical site, the drugs leach out and are delivered directly to the surgical site as demonstrated by Tague et al. (col. 1, lines 32-37).

Accordingly it would have been obvious to have mixed a desired drug into the bone cement prior to delivery of the bone cement utilizing the method of Li et al. since it was well known in the art to mix a specific drug in bone cement prior to delivery of the bone cement to a specific surgical site so that the drug is delivered directly to the surgical site.

The method steps of claim 25 are rendered obvious by the above discussion.

Claims 35, 43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (US 6,622,731) in view of Tague et al. (US 6,599,293).

Daniel et al. disclose all elements of the claimed invention except for providing a medicament or drug in the bone cement.

It is well known to mix antibiotics or other desired drugs in bone cement so that when the bone cement is applied to a specific surgical site, the drugs leach out and are delivered directly to the surgical site as demonstrated by Tague et al. (col. 1, lines 32-37).

Accordingly it would have been obvious to have mixed a desired drug into the bone cement prior to delivery of the bone cement utilizing the method of Daniel et al.

since it was well known in the art to mix a specific drug in bone cement prior to delivery of the bone cement to a specific surgical site so that the drug is delivered directly to the surgical site.

The method steps of claims 35, 43 and 50 are rendered obvious by the above discussion.

Claims 28, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorek (US 6,752,809).

Gorek discloses all of the claimed steps except for: (1) partially or completely withdrawing the bone tap; and (2) introducing fluid to a first location, moving the bone tap and introducing fluid to a second location.

It is well known that during a surgical procedure if the chosen direction of insertion does not result in easy access to the target site, for example, due to the nature of the underlying bone, the surgeon would need to change the direction of insertion.

The claimed method steps are within the purview of obvious design choice because partial or complete withdrawal of the bone tap might be necessary if the surgeon made an error in placement of the bone tap. Further, moving from one location to another might require either complete or partial withdrawal of the bone tap, i.e., moving of the bone tap, depending on the proximity of the first and second locations, based on the nature of the underlying bone.

Claims 28, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US 6,610,079).

Li et al. disclose all of the claimed steps except for: (1) partially or completely withdrawing the bone tap; and (2) introducing fluid to a first location, moving the bone tap and introducing fluid to a second location.

It is well known that during a surgical procedure if the chosen direction of insertion does not result in easy access to the target site, for example, due to the nature of the underlying bone, the surgeon would need to change the direction of insertion.

The claimed method steps are within the purview of obvious design choice because partial or complete withdrawal of the bone tap might be necessary if the surgeon made an error in placement of the bone tap. Further, moving from one location to another might require either complete or partial withdrawal of the bone tap, i.e., moving of the bone tap, depending on the proximity of the first and second locations, based on the nature of the underlying bone.

Claims 39, 41 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (US 6,622,731).

Daniel et al. disclose all of the claimed steps except for partially withdrawing the bone tap.

It is well known that during a surgical procedure if the chosen direction of insertion does not result in easy access to the target site, for example, due to the nature of the underlying bone, the surgeon would need to change the direction of insertion.

The claimed method steps are within the purview of obvious design choice because moving to a specific location or moving from one location to another might require either complete or partial withdrawal of the bone tap, depending either on: (1) whether the surgeon made an error in approaching the target site; and/or (2) on the proximity of the first and second locations.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on April 25, 2008 have been fully considered but are not persuasive for the following reasons.

Regarding the rejections over Gorek, as explained in this and the previous office action, Gorek discloses all elements of Applicant's claimed invention. Threaded cannula 100 is being interpreted to be a bone tap. Applicant's claim does not positively recite the step of creating a passageway in bone using the bone tap. Further, the

claimed method does not preclude the bone tap from being left in place for introduction of the fastener.

Regarding the rejections over Li, it is noted again that Applicant's claim does not positively recite the step of creating a passageway in bone using the bone tap. Further, the claimed method does not preclude the bone tap from being left in place for introduction of the fastener.

Regarding the rejections over Daniel, contrary to Applicant's arguments, Daniel discloses all elements of Applicant's claimed invention. Daniel discloses intraosseous injection of fluids such as bone cements (col. 20, lines 25-45). Regarding the limitation, "removable driver", Daniel discloses handpiece 296 to be coupled or "removably attached" to the proximal end of the introducer (col. 22, lines 7-23).

The Examiner notes that to be entitled to weight in method claims, the recited structural limitations must affect the method in a manipulative sense, and not amount to the mere claiming of a use of particular structure. Ex parte Pfeiffer, 1962 C.D. 408 (1961). Therefore, use of terms such as "bone tap," "removable driver" etc. must affect the method in a manipulative sense.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

July 17, 2008

/Anu Ramana/
Primary Examiner, Art Unit 3733